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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,883	12/21/2000	Hans-Ulrich Demuth	20784-5	1277

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,883

Applicant(s)

DEMUTH ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 14 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 14 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. The finality of the previous Office Action is withdrawn due to a new ground of rejection.

Status of the Claims

2. Claims 1-8, 14 and 16 are pending.

Applicants' amendment filed July 30, 2004 is acknowledged. Applicants' response has been fully considered. Claim 14 has been amended, and claims 9-13 and 15 have been cancelled. Thus, claims 1-8, 14 and 16 are examined.

Oath/Declaration

3. A new oath/declaration filed July 30, 2004 is acknowledged.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

4. The previous rejection of claims 9-13 and 15, under 35 U.S.C.112, first paragraph is withdrawn in view of applicants' cancellation to the claims, and applicants' response at pages 5-6 in the amendment filed July 30, 2004.

Informalities

The disclosure is objected to because of the following informalities:

5. The specification cites "azetidinecarboxylic acid or aziridinecarboxylic acid" (page 8, lines 29), where the position of the carboxylic acid group is not indicated in the compound. Appropriate correction is required.
6. The specification cites "examples of the dipeptide group, for example Ile-Thia, Ile-Pyr, Val-Thia and Val-Pyr" at page 5, line 23, however, the Thia or Pyr group does not contain a

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carboxylic group and it is not an amino acid, thus Ile-Thia, Ile-Pyr, Val-Thia and Val-Pyr are not dipeptides. Appropriate correction is required.

Claim Objections

7. Claim 2 is objected to because of the use of the term “azetidinecarboxylic acid or aziridinecarboxylic acid”, where the position of the carboxylic acid group is not indicated in the compound. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-8, 14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-8, 14 and 16 are indefinite because of the use of the term “unstable inhibitor of DP IV”. The term “unstable inhibitor of DP IV” renders the claim indefinite, it is unclear what the term means since neither the specification nor the claim defines the term, e.g., how unstable the inhibitor is, and what criteria are used to decide the inhibitor being unstable. The claim cites the term “unstable inhibitor is a dipeptide compound having C-terminus with an active carbonyl group”, which merely indicates the structure of the inhibitor, it does not define the term “unstable inhibitor”. Since the dipeptide contains an active carbonyl group, not a boronate or phosphonate group, it is not clear why the claim recites the term “unstable inhibitor does not contain a boronate, phosphonate”. Claims 2-8 and 14 are included in the rejection because they

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are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

9. Claim 4 is indefinite as to whether the unstable inhibitor is a dipeptide or not. Claim 4 indicates the unstable inhibitor is a dipeptide compound which is Ile-Thiazolidine, Ile-Pyrrolidine, Val-Thiazolidine or Ile-Pyrrolidine, however, the Thiazolidine or Pyrrolidine is not an amino acid, thus, Ile-Thiazolidine, Ile-Pyrrolidine, Val-Thiazolidine or Ile-Pyrrolidine is not a dipeptide.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 8 and 14 are rejected under 35 U.S.C. 102(b) as anticipated by Bachovchin *et al.* (WO 95/11689).

Bachovchin *et al.* disclose an inhibitory compound of DP IV having a structure of Group I-Group II, where Group I contains unblocked peptide, and Group II contains a boronate, a phosphonate or a fluoroalkyl (e.g., trifluoroalkyl or difluoroalkyl, see page 4, line 16-page 5, line 1) ketone group which is covalently to Pro or a Pro analog (page 2, line 33-page 5, line 22; Fig. 1), and the preferred inhibitory compound includes an amino acid sequence having the cleavage site of a DP IV substrate, thus the cleavage product of the inhibitory compound also inhibits DP IV (page 8, line 29- page 9, line 17; claims 1 and 14). The inhibitory compound is admixed with a pharmaceutical acceptable carrier (page 5, lines 20-21; claim 8).

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Conclusion

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

CMK
August 12, 2004

Jon P. Weber
Supervising Jon P. Weber, Ph.D.
Primary Examiner